4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0827]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Ila S. Mizrachi,

Office of Information Management,

Food and Drug Administration,

1350 Piccard Dr.,

PI50-400B,

Rockville, MD 20850,

301-796-7726,

Ila.Mizrachi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma--(OMB Control Number 0910-NEW)

FDA is finalizing the labeling requirements for blood or blood components intended for use in transfusion or for further manufacture under the provisions of the Public Health Service Act (PHS Act) (42 U.S.C. 262-264), and the drugs, devices, and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 331, 351-353, 355, 360, 360j, 371, and 374). Under these provisions of the PHS Act and the FD&C Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, potent, and properly labeled, and to prevent the introduction, transmission, and spread of communicable disease.

Under this rulemaking, FDA is consolidating the regulations related to labeling blood and blood components. Regulations for labeling of blood and blood components will be

consolidated into § 606.121 (Container label) (21 CFR 606.121) and § 606.122 (Circular of information) (21 CFR 606.122). This notice solicits comments on the information collection associated with § 606.121(c)(11), which requires that if the product is intended for further manufacturing use, a statement listing the results of all the tests for communicable disease agents required under § 610.40 (21 CFR 610.40) for which the donation has been tested and found negative must be on the container label; except that the label for Source Plasma is not required to list the negative results of serological syphilis testing under § 610.40(i) and 21 CFR 640.65(b). In addition, this notice also solicits comments on the information collection associated with § 606.121(e)(2)(i), which requires that the product labels of certain red blood cells must include the type of additive solution with which the product was prepared.

The Agency believes the rule amendments and the information collection provisions under § 606.121(c)(11) and (e)(2)(i) in the final rule are part of usual and customary business practice and do not create any new burden for respondent.

The collection of information requirements under §§ 606.121 and 606.122 are approved under OMB control number 0910-0116 and those in 21 CFR 640.70 have been approved under OMB control number 0910-0338. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

In the Federal Register of December 30, 2011 (76 FR 82300), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Dated: April 19, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-9894 Filed 04/24/2012 at 8:45 am; Publication Date: 04/25/2012]